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	2003 2000		Archives of Bioche	emistry and Biophysic	s, 402 (2002), pp. 249	-254; published L	by Eisevier 30		,		
Bickston, S.J. et al., "Recombinant Interleukin 10 for the Treatment of Active Crohn's Disease Biologic Therapy," Gastroenterology, 119 (6) (2000), pp. 1781-1783; published by American Gastroenterological Association (USA). Cantorna, M. T. et al., "1,25-Dihydroxycholecalciferol Prevents and Ameliorates Symptoms of Murine Inflammatory Bowel Disease," J. Nutr., 130 (2000), pp. 2648-2652; published by American Colombel, J-F. et al., "Interleukin 10 (Tenovil) in the prevention of postoperative recurrence of disease," Gut, 49 (2001) pp. 42-46; published by British Medical Association (United Kingdom						e: Lessor	ns in				
						s Symptoms o lished by Am	of Experim erican Soc	ental ciety for			
						e of Crohn's dom).					
	Cornillie, F. et al., "Infliximab induces potent anti-inflammatory and local immunomodulatory activity be systemic immune suppression in patients with Crohn's disease," Aliment Pharmacol Ther., 15 (2001) 473; published by Blackwell Science Ltd.							activity bu	ut no pp. 463-		
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Page 2 of 3

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Form PTO-1449	U.S. DEPARTMENT OF COMMERCE	ATTY, DOCKET NO.	SERIAL NO.
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THAT THAT THE	Ol B "Consor	seus for infliximal treatment of patient	ts with Crohn's disease"], Ned
	Tijdschr. Geneeskd., 144 (38) (2000), pp 1845 of the reference.	o. 1844-1845 (Netherlands). English /	Abstract is provided on page
	van Deventer, S. J. et al., "Multiple Dose	s of Intravenous Interleukin 10 in Ster	roid-Refractory Crohn's Disease,"
	Gastroenterology, 113 (2) (1997), pp. 38	3-389; published by American Gastro	enterological Association (USA).
	Harries, A.D. et al., "Vitamin D status in	Crohn's disease: association with nu	trition and disease activity," Gut,
	26 (1985), pp. 1197-1203.		
	Issenman, R. M., "Bone Mineral Metabol (3) (1999), pp. 192-199; published by Cr	ism in Pediatric Inflammatory Bowel I ohn's & Colitis Foundation of America	Disease," <i>Inflamm. Bowel Dis.</i> , 5 a, Inc. (USA).
•			
	Jahnsen, J. et al., "Vitamin D Status, Pa	rathyroid Hormone and Bone Mineral	Density in Patients with
	Inflammatory Bowel Disease," Scand. J.	Gastroenterol., 37 (2002), pp. 192-18	99, published by rayler a rance.
	/ Kirchgatterer, A. et al., "Examination, Pr	Treatment of Octoopera	cie in Patients with Inflammatory
ì	Bowel Disease: Recommendations and Copyright Clearance Center Code State	Reality," Acta Medica Austriaca, 29 (2002), pp. 120-123; U.S.
			w t gamester bound
	Lamb, E. J. et al., "Metabolic bone disea disease," Aliment Pharmacol. Ther., 16	ase is present at diagnosis in patients (2002), pp. 1895-1902; published by	With Inflammatory bowel Blackwell Science Ltd.
	disease," Aliment Pharmacol. Ther., 16	(2002), pp. 1093-1902, pasiisiioo by	
gr	Scharla, S. H. et al., "Bone mineral dens bowel disease (Crohn's disease and ulc published by Johann Ambrosius Barth.	sity and calcium regulating hormones erative colitis)," Exp. Clin. Endocrinol	in patients with inflammatory ., 102 (1994), pp. 44-49;
5	published by donarity this reside Barrier		
•	Schulte, C. et al., "Reduced Bone Miner Inflammatory Bowel Disease," Inflamm. Foundation of America, Inc. (USA).	al Density and Unbalanced Bone Met Bowel Dis., 4 (4) (1998), pp. 268-275	abolism in Patients with published by Crohn's & Colitis
1	Foundation of America, inc. (OOA).		
	Silvennoinen, J., "Relationships betwee inflammatory bowel disease," J. Intern.	n vitamin D, parathyroid hormone and Med., 239 (2) (1996), pp. 131-137; pu	d bone mineral density in ablished by Blackwell Science Ltd.
	Sonnenberg, A. et al., "25-Hydroxycholo Hepato-Gastroenterol., 24 (1977), pp. 2	ecalciferol Serum Levels in Patients w	rith Crohn's Disease," Acta Verlag Stuttgart (Germany).
	nepato-Gastroenteror., 24 (1977), pp. 2	20 200, published by Goolg	
	Vogelsang, H. et al., "Bone Disease in V	Vitamin D-Deficient Patients with Crol	nn's Disease," Digestive Diseases
APR H CEN		1099; published by Plenum Publishing	g Corporation (USA).
显 2 1	Vogelsang, H. et al., "25-Hydroxyvitami insufficiency," Wien Klin Wochenschr.,	n D. absorption in patients with Crohr 109 (17) (1997), pp. 678-682; publish	n's disease and with pancreatic ed by Springer-Verlag (Austria).
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